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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/820,420	03/29/2001	Herbert B. Slade	55507USA002	5602

7590 08/13/2002

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EXAMINER
HUI, SAN MING R

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/820,420	SLADE, HERBERT B.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendments of claims 1, 9, 14, 22, and 25 filed May 13, 2002 is acknowledged.

Claims 1-26 are pending.

The outstanding rejections under 35 USC 112, first paragraph are withdrawn in view of the amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "the source of envenomation" in line 1. There is insufficient antecedent basis for this limitation in the claim. Examiner would favorably considered the phrase "venom induced immune dysregulation".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tomai et al. (WO 98/17279) and Gerster et al. (US Patent 6,110,929) in view of Bitterman-Deutsch et al. (HAREFUAH, 1990; 119(5-6):137-139), Mosbech et al. (Ugeskrift for Laeger, 1991;153(44):3067-3071), Binder (Medical Toxicology and Adverse Drug Experience, 1989;4(3):163-173), and Auerbach et al. (Journal of Emergency Medicine, 1987;5(6):487-491), references of record in the previous office action mailed January 2, 2002.

Tomai et al. teaches imidazoquinoline amine compounds including 4-amino-2-ethoxymethyl-α,α -dimethyl-1H-imidazo[4,5-c]quinoline-1-ethanol and 1-(2-methylpropyl)-1H-imidazo[4,5-c]quinolin-4-amine, preferred compounds herein, can inhibit T-cell Type-2 activities (See particularly the abstract,page 2, line 5-20, page 12, line 13-20, clam 17). By inhibiting the activities of T-cell Type 2, it can also reduce the production of cytokines such as interleukin-3, interleukin-4, and interleukin-5, and the production of IgE and esinophils activities thereby (See particularly the abstract, page 2, line 5-20, page 12, line 13-20, clam 17). Tomai et al. also teaches that IgE is the important component of allergic reaction (See particularly page 12, line 13-20). Tomai et al. also teaches that the imidazoquinoline amine compounds including 4-amino-2-ethoxymethyl- α,α-dimethyl-1H-imidazo[4,5-c]quinoline-1-ethanol may be administered via topical route as topical cream or gel (See particularly page 3, line 14-15).

Gerster et al. teaches thiazoquinoline compounds including 2-methylthiazolo[4,5-c]quinolin-4-amine, 2-ethylthiazolo[4,5-c]quinolin-4-amine, 2-propylthiazolo[4,5-c]quinolin-4-amine, and 2-butylthiazolo[4,5-c]quinolin-4-amine, preferred compounds herein, can inhibit T-cell Type-2 activities and be useful in wound treatment (See particularly the abstract; col.6, line 41-46; also also col. 14, ine 63-64). Gerster et al. also teaches that the thiazoquinoline compounds may be formulated into topical creams and ointments (See col. 13, line 49).

The references do not expressly teach the imidazoquinoline and thiazoquinoline compounds are useful in treating and/or preventing dermal lesions by venom induced immune dysregulation caused by spider, jellyfish and insect of the order Hymenoptera.

Bitterman-Deutsch et al. teaches that lesions caused by brown recluse spider envenomation may be treated by dapsone, which presumably acting by reducing the activity of polymorphonuclear leukocytes (See particularly abstract).

Mosbech et al. teaches that bee or wasp sting could result in allergic reactions (See the abstract).

Binder teaches that local treatment of Black widow spider envenomations includes local wound care (See particularly abstract). Binder also teaches that Black widow spider envenomation could cause cell membrane lyses and the release of chemotaxis (See the abstract).

Auerbach et al. teaches that jellyfish envenomation could cause intense dermatitis that is responsive to local and systemic mild immunosuppressive agent corticosteroid (See the abstract).

It would have been obvious to one skill in the art when the invention was made to employ the imidazoquinoline and thiazoquinoline compounds herein in a method of treating and preventing dermal lesions by venom induced immune dysregulation, in particular caused by spider, jellyfish and insect of the order Hymenoptera.

One of ordinary skill in the art would have motivated to employ the imidazoquinoline and thiazoquinoline compounds herein in a method of treating and preventing dermal lesions by venom induced immune dysregulation, in particular caused by spider, jellyfish and insect of the order Hymenoptera because the imidazoquinoline and thiazoquinoline compounds herein are known to be useful in treating diseases by T-cell type 2 inhibition, esinophils (polymorphhnuclear leukocyte) inhibition, and IgE inhibition. Therefore, employing the imidazoquinoline and thiazoquinoline compounds herein to treat or prevent dermal lesions caused by brown recluse spider or black widow spider envenomation would be reasonably expected to be effective since blocking polymorphhnuclear leukocyte activities and chemotaxis is an effective treatment module for the spider envenomation, regardless of the underlying mechanism of action of how the dermal lesions developed. Furthermore, absent evidence to the contrary, employing the imidazoquinoline and thiazoquinoline compounds herein to treat or prevent dermal lesions caused by jellyfish and bee envenomation would be reasonably expected to be effective regardless of the underlying mechanism of action of how the dermal lesions developed since the imidazoquinoline and thiazoquinoline compounds herein are known to be useful in

blocking IgE and esinophil activities, which is an important component for allergic dermatitis.

It is applicant's burden to demonstrate unexpected results over the prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, the data of the example in the instant specification, page 6-10 merely demonstrate the effectiveness of the compounds herein to treat envenomation. This is seen to be an expected effect based on the cited prior art. No convincing and clear unexpected result is seen.

Response to Arguments

Applicant's arguments filed May 13, 2002 averring the cited prior art's failure to teach the cause of the dermal lesions, have been fully considered but they are not persuasive. As discussed above, possessing the teachings of the cited prior art, one of ordinary skill in the art would employ the instant compounds to treat dermal lesions caused by envenomation of spider, jellyfish and bee, regardless of the underlying mechanism of action of how the lesions developed, absent evidence to the contrary.

Applicant's arguments filed May 13, 2002 averring the immune response modifier compounds herein claimed are stimulants and have multiple effects in the immune response have been fully considered but they are not persuasive. The cited prior art clearly teaches the instant compounds can inhibit immunological mediators such as the cytokines and immunoglobulins.

Applicant's arguments filed May 13, 2002 averring dapone is a completely different compound than the immune response modifier compounds herein have been considered but are not found persuasive. Dapone, as Bitterman-Deutsch et al. teaches, presumably acts by reducing the activity of polymorphonuclear leukocytes in envenomation treatment. Therefore, one of ordinary skill in the art would reasonably expect employing compounds known to inhibit the activities of polymorphonuclear leukocytes such as the imidazoquinoline and thiazoquinoline compounds herein in treating the dermal lesions caused by envenomation, absent evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Russell Travers, J.D., can be reached on (703) 308-4603. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
July 30, 2002

RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200